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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/167,516 10/06/98 CHEEVER

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EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

08/15/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/167,516

Applicant(s)

Cheever et al

Examiner

Karen Canella

Art Unit

1642



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 7-12 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 7-12 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

20) ☐ Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 7-12 are under consideration.

New Claim Rejections

3. Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 7(b) recites "amino acid sequence which is identical to a portion of Her-2/neu protein" without defining what portion of Her-2/neu is encompassed by the claim.

(B) The recitation of "cells" in claims 8 and 9 has no antecedent basis in claim 7.

4. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for eliciting or enhancing an immune response to the intracellular portion or the Her-2 protein comprising the infection or transfection of autologous antigen presenting cells, and the subsequent administration of said antigen presenting cells, does not reasonably provide enablement for infection or transfection of non-antigen presenting cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification describes the claimed nucleic acids as encoding the intracellular portion of the Her-2 antigen. The specification teaches that the protein expressed from nucleotides 2026-3765 of SEQ ID NO:1 is effective in priming dendritic cells which can induce the proliferation of autologous Cd+4 T cells in vitro. The specification teaches that rats immunized with Her-2/neu polypeptide develop neu specific antibodies. The declaration of Paper No. 16 provides evidence that dendritic

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cells infected with a viral vector comprising nucleotides 2026-3765 of SEQ ID NO:1 were effective at generating CTL in vitro. The specification does not teach that infection or transfection of any other cell type beyond antigen presenting cells could be useful at generating an immune response against the intracellular portion of the Her-2 antigen. One of skill in the art would be subject to undue experimentation in order to practice the invention as broadly claimed.

5. All other rejections and objections as stated in Paper No. 13 are withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
August 12, 2001


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SUPERVISORY PATENT EXAMINER
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